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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/700,313	10/31/2003	Christophe Combadiere	4239-66645	5461

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EXAMINER	
ULM, JOHN D	

ART UNIT	PAPER NUMBER
1649	

DATE MAILED: 10/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/700,313	COMBADIERE ET AL.	
	Examiner	Art Unit	
	John D. Ulm	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-24* is/are pending in the application.

4a) Of the above claim(s) *13-17 and 20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-12,18,19 and 21-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/03/04, 07/28/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1) Claims 6 to 24 are pending in the instant application.

2) Claims 13 to 17 and 20, and claims 18 and 21 to 24 in so far as they relate tro a method of treating by administering a nucleic acid, are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 29 August of 2005. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

3) The drawings in the instant application do not comply with 37 C.F.R. § 1.821(d), which requires a reference to a particular sequence identifier (SEQ ID NO:) be made in the specification and claims wherever a reference is made to that sequence. Figure 1A of the instant application presents three amino acid sequences, of which only one is identified by a sequence identifier. M.P.E.P. 2422.02 expressly states that "when a sequence is presented in a drawing, regardless of the format or the manner of presentation of that sequence in the drawing, the sequence must still be included in the Sequence Listing and the sequence identifier ("SEQ ID NO:X") must be used, either in the drawing or in the Brief Description of the Drawings". Correction is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4) Claims 6 to 12, 18, 18 and 21 to 24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description and enablement

requirements. These claims encompass subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention and in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

First, it is fairly well established in the art that CCR5 is not essential for the infection of any and all susceptible cells by any and all types of HIV. As indicated by the text on pages 2 and 3 of the instant specification, the co-expression of CD4 and CXCR4 by a cell is sufficient to render that cell susceptible to infection by T-cell line tropic HIV-1 isolates. One would not reasonably expect the administration of a CCR5 blocking agent to such a cell to have any predictable effect on the fusion of that cell to HIV. Therefore, the instant specification only provides the guidance needed to inhibit fusion between HIV and a target cell if that target cell, or CD4 positive uninfected cell, expresses CCR5.

Second, the genus of "agents" encompassed by the limitation "CCR5 binding or blocking agent" or "agent that suppresses CCR5". Whereas the instant specification describes three different classes of proteins consisting of chemokines, antibodies, and peptides corresponding to the three extracellular loops of CCR5, the recited limitations are not limited to peptides, organic compounds, inorganic compounds or even material entities. Ionizing radiation or a denaturing level of heat would certainly inhibit the interaction of HIV with CCR5, but the instant specification does not provide the guidance needed to employ such agents in the claimed process. In the decision of *The*

Regents of the University of California v. Eli Lilly and Company, 43 USPQ2d 1398 (CAFC 1997), the court held that:

> "To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc. , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood , 107 F.3d at 1572, 41 USPQ2d at 1966.
>
> An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel , 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

The only agents that are described in the instant specification "by structure, formula, chemical name, or physical properties" are blocking anti-CCR5 antibodies or binding fragments thereof, peptides comprising those sequences presented in SEQ ID NO:4, 5 and 6 of the instant application, RANTES, MIP-1α, or MIP-1β. Whereas it is almost a certainty that other CCR5 blocking compounds will be identified, the instant specification does not provide a description of the genus of such compounds that is sufficient to determine if a compound currently being employed to treat HIV infections is inherently encompassed by the limitation "CCR5 binding or blocking agent" or "agent that

suppresses CCR5". The discovery of an inherent property of a prior art process can not serve as a basis for patenting that process. See *Ex parte Novitski*, 26 USPQ2d 1389 (Bd. Pat. App. & Inter. 1993) (The Board rejected a claim directed to a method for protecting a plant from plant pathogenic nematodes by inoculating the plant with a nematode inhibiting strain of *P. cepacia*. A U.S. patent to Dart disclosed inoculation using *P. cepacia* type Wisconsin 526 bacteria for protecting the plant from fungal disease. Dart was silent as to nematode inhibition but the Board concluded that nematode inhibition was an inherent property of the bacteria. The Board noted that applicant had stated in the specification that Wisconsin 526 possesses an 18% nematode inhibition rating.). Because the instant specification does not provide an adequate description of the genus of molecules that are encompassed by the term "CCR5 blocking or binding agent", one can not determine if a prior art process is inherently encompassed by the instant claims

In so far as claims 18, 19 and 21 to 24 encompass a method of treatment by administering a blocking "agent that suppresses CCR5" expression, given that there is absolutely no evidence of record that the administration of a blocking agent to any G protein-coupled receptor results in a reduction in the level of expression of that protein, one of ordinary skill in the art of molecular biology would have no expectation that the administration of a CCR5 blocking agent to an individual would suppress the expression of that protein. The instant specification provides no working examples or sound scientific reasoning that supports a conclusion to the contrary. Further, in so far as these claims encompass a method of treating by administering a CCR5 blocking agent

into a cell, it is well known in the art that the site of action for agents that block the action of a G protein-coupled receptor, such as CCR5, is found on the surface of a cell. It is noted that the only method of blocking the interaction of HIV or an HIV-infected cell with a CCR5 molecule of the instant invention is through the exogenous administration of a CCR5 blocking agent. Therefore, one does not have a reasonable expectation that the introduction of a CCR5 blocking agent into a cell would have any effect on the interaction of HIV or an HIV-infected cell with a CCR5 molecule.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5) Claims 11, 18, 19 and 21 to 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5.1) Claim 11 is vague and indefinite because there is no antecedent basis for "the anti-CCR5 antibody"

5.2) Claims 18, 19 and 21 to 24 are vague and indefinite because the limitation "suppresses" requires a reference to the activity or activities being suppressed and no such activity is recited in these claims.

5.3) Claim 22 is vague and indefinite because there is no antecedent basis for "the carrier".

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6) Claims 6 to 12, 18, 19 23 and 24 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by the Allaway et al. patent (6,344,545). See claim 2 of Allaway et al.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7) Claims 6, 9, 18, 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Cocchi et al. publication (SCIENCE 270:1811-1815, 15 Dec. 1995, cited by Applicant). The Cocchi et al. publication expressly identified the naturally occurring chemokines RANTES, MIP-1α and MIP-1β as soluble HIV suppressive factors. The text on page 29 of the instant specification explicitly identifies RANTES, MIP-1α and MIP-1β as being encompassed by the limitation "CCR5-binding agent". Because one of ordinary skill in the art would have recognized the desirability of suppressing HIV activity in an individual infected with HIV, they would have found it *prima facie* obvious to administer RANTES, MIP-1α, and/or MIP-1β to that individual to inhibit HIV activity.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (571) 272-0880. The examiner can normally be reached on 9:00AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JOHN ULM
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